CERCLA Baseline Risk Assessment Human Health Evaluation

BACKGROUND: **This Information Brief presents the basic concepts and essential information for planning and managing a risk assessment task under the Comprehensive Environmental Response, Compen- sation, and Liability Act(CERCLA). Using the data developed under the remedial investigation (RI), DOE must conduct a site-specific baseline risk assessment to characterize the current and potential threats to human health and the environment that may be posed by contaminants released to and/or migrating within the environmental media. The overall objective of a CERCLA risk assessment is to provide risk-based information to the environmental restoration project managers (ERPMs) for remedial decision making (i.e., deciding whether or not remediation of a site may be needed because of potential threats to human health).**

STATUTES: **Comprehensive Environmental Response, Compensation, and Liability Act, Section 104 (Response Actions), Section 120 (Federal Facilities), and Section 121 (Cleanup Standards).**

REGULATIONS: **40 CFR 300.430(d); 40 CFR 300.430(e).**

REFERENCES:

1."Risk Assessment Guidance for Superfund, Volume 1: Human Health Evaluation Manual (Part A, Baseline Risk Assessment)," EPA/540/1-89/002 (12/89).

2."Risk Assessment Guidance for Superfund, Volume 1: Human Health Evaluation Manual Supplemental Guidance,Standard Default Exposure Factors,"OSWER Directive No.9285.6-03(3/91).

3."Superfund Exposure Assessment Manual,"EPA/540/1-88/001,OSWER Directive 9285.5-1 (4/88).

4."Guidance for Data Useability in Risk Assessment(Interim Final)," EPA/540/G-90/008 (10/90).

5."Guidance for Conducting Remedial Investigation and Feasibility Studies Under CERCLA," EPA/540/G-89/004,OSWER Directive No.9355.3-01 (10/88).

6."Integrated Risk Information System," DOE/EH--0194 (6/91).

7."Guidance on Risk Characterization for Risk Managers and Risk Assessors." Memorandum from Deputy Administrator, U.S.EPA, to Assistant Administrator and Regional Administrators, U.S.EPA, February 26, 1992.

8."Guidance for Exposure Assessment," EPA/600-Z-92/001, May 29, 1992.

What is a risk assessment?

A risk assessment is an evaluation of the potential adverse impact of a given event(e.g.,the release or threat of release of a hazardous substance) upon the well-being of a person or a population. It is a process by which information or experience concerning the cause and effect under a set of circumstances (e.g., exposure) is integrated with the extent of those circumstances to quantify or otherwise describe risk.

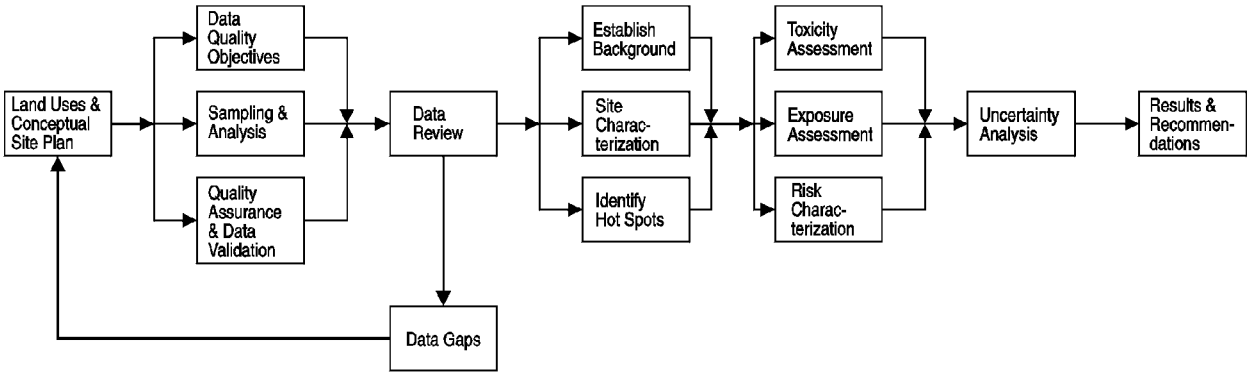
What are the components of a risk assessment in the context of environmental protection?

According to the concept established by the National Academy of Sciences in 1983, a risk assessment consists of four basic components: (1) hazard identification, (2) dose-response evaluation, (3) exposure assessment, and (4) risk characterization/uncertainty analysis. The last component integrates information collected under the first three. Essentially, these components address the following questions:

- What are the contaminants and their known or possible modes of actions?
- What is the cause-effect relationship between exposure and human health impact from each contaminant?
- Who is being or may possibly be exposed to the contaminants and what is the nature and magnitude of exposure?
- How "bad" is the site;i.e., does it pose an unacceptable human health risk *if no remedial action is taken*?

What is a CERCLA baseline risk assessment?

Under Sections 104 and 121 of CERCLA,the U.S. Environmental Protection Agency (EPA) is required to assess the risks to human health posed by uncontrolled hazardous waste sites on the National Priorities List (NPL). That assessment is conducted in the remedial investigation/feasibility study (RI/FS) phase of the site cleanup process. When applied to the evaluation of human health impacts caused by uncontrolled CERCLA sites (i.e., no remedial action is taken), this process is termed the "baseline risk assessment."



Risk Assessment Process in the CERCLA RI/FS

How does a CERCLA risk assessment differ from a public health assessment conducted by the Agency for Toxic Substances and Disease Registry(ATSDR)?

Conceptually, a public health assessment authorized under CERCLA Section 104(i)(6) and conducted by ATSDR is similar to a CERCLA baseline risk assessment conducted by EPA or other lead agencies. In conducting a health assessment, ATSDR usually utilizes site data and exposure point concentrations collected by the lead agency to evaluate the threat to human health posed by the site. In the health assessment, the exposure point concentration of the hazardous substance, or the amount to which a receptor is exposed per day, is compared with established health standards.

A health assessment is a mechanism to respond to community health concerns associated with human exposure to site contaminants. It may be less quantitative than a CERCLA risk assessment in terms of exposure modeling, fate and transport evaluation, and pathway-specific quantification of risks and hazards. Based on the health assessment, ATSDR may issue a health advisory, recommend actions to reduce public health threat, and/or identify studies to further evaluate the health impact from a site.

What are the objectives of a superfund risk assessment?

Specific objectives of a CERCLA risk assessment are the following:

- Identify the areas of concern due to the existence of hazardous substances
- Identify the environmental media of concern due to the potential exposure to humans
- Characterize the potential carcinogenic risk and noncarcinogenic hazard
- Allow the identification of key hazardous substances that contribute significant risk (principal threat)
- Allow the calculation of health-based cleanup levels for hazardous substances that do not have cleanup standards applicable to the environmental media of concern at the site
- Allow the evaluation of potential risks to humans from various remedial alternatives prior to their selection

What steps should an ERPM take to ensure that a CERCLA risk assessment is properly conducted?

Involvement of risk assessors in early planning (project scoping) is key. Without such involvement, data collected may be insufficient or inappropriate for risk assessment. An improperly conducted CERCLA risk assessment may lead to biased or inaccurate information for decision making; the resulting inaction or unnecessary action may jeopardize human health or divert limited resources away from sites that truly need remediation.The following steps are recommended to ensure that a CERCLA risk assessment is well conducted:

- Identify current and potential future land uses, and on-site and off-site population characteristics
- Establish the conceptual site model (i.e., the exposure model - the combination of all complete exposure pathways and routes of exposure that enable the site hazardous substances to enter the human receptor)
- Focus on data needs and data quality objectives based on understanding of the conceptual model
- Design a sampling and analysis plan (SAP) and a quality assurance project plan (QAPP) to define the nature and extent of contamination and to establish background concentrations
- Review and validate laboratory data according to EPA Contract Laboratory Program statement of work
- Compile data, apply appropriate statistical treatment to address spatial and temporal variability, and identify "hot spot" areas
- Establish exposure point concentrations or calculate concentrations by the appropriate exposure release/dispersion or bioaccumulation models

- Examine all exposure assumptions for reasonableness and document site-specific exposure information
- Collect up-to-date toxicity information for site hazardous substances and critically review the corresponding EPA level of confidence rating (noncarcinogens) and weight-of-evidence classification (carcinogens)
- Characterize medium-specific noncarcinogenic hazards and carcinogenic risks for each human receptor based on complete exposure pathways that could impact the receptor
- Characterize uncertainties qualitatively or quantitatively
- Describe the risk assessment logically and concisely, present results objectively, identify possible data gaps,and recommend future actions to reduce uncertainties.

How is the noncarcinogenic hazard evaluated?

The noncarcinogenic hazard posed by a hazardous substance is the average daily intake divided by the reference dose(RfD);this ratio is known as the hazard quotient(HQ). The average daily intake is the mass of a hazardous substance contacted per unit body weight per unit time averaged over a portion of a lifetime (i.e., that portion of a lifetime during which exposure actually occurs). RfDs are developed for chronic, subchronic, and single-event intakes. A chronic RfD is an estimate (with uncertainty spanning perhaps an order of magnitude)of the highest average daily exposure to a member of the human population (including sensitive subpopulations) that will not result in deleterious effects during a lifetime. Subchronic RfDs define the highest average daily exposure over shorter time periods (i.e., between 2 weeks and 7 years) that will not cause adverse health effects. Developmental RfDs estimate the highest single-event exposure level that will not be deleterious to a developing organism. HQ (unitless) is expressed as:

$$HQ = Intake/RfD$$

For multiple hazardous substances in an exposure path-way, the total pathway-specific noncarcinogenic hazard is the sum of HQs from all noncarcinogens.

How is the carcinogenic risk evaluated?

The carcinogenic risk posed by a hazardous substance is the average daily intake multiplied by the carcinogenic slope factor (SF);this multiplication product is known as the upper bound individual excess lifetime cancer risk (cancer risk above the background cancer risk due to exposure to other carcinogens not related to the site). The risk estimate is upper bound because it is an estimate based on conservative dose-response modeling and the true risk may in fact be lower. The average daily intake is the mass of a hazardous substance contacted per unit body weight per unit time averaged over an assumed lifetime of 70 years.The SF is an upper bound estimate of cancer risk per mass of a hazardous substance contacted per unit body weight per day (expressed in units of $(mg/kg/day)^{-1}$). SFs are estimated through the use of mathematical extrapolation models for estimating the largest possible linear slope (within the 95% confidence limit) at low extrapolated doses that is consistent with the data. Carcinogenic risk estimate (unitless) is expressed as:

$$Risk = Intake \times SF$$

For multiple hazardous substances in an exposure path-way, the total pathway-specific carcinogenic risk is the sum of carcinogenic risks from all carcinogens.

What are some of the common errors or problems found in a CERCLA risk assessment?

Unrealistic exposure assumptions can exaggerate site risks, leading to stringent cleanup goals that could be set below the routine capabilities of the analytical laboratory. The following is a list of common CERCLA risk assessment errors:

On hazard identification:

- Inclusion of background hazardous substances or failure to address background hazard or risk
- Inadequate application of quality assurance,which may result in the incorporation of intra-laboratory contaminants levels in the reported site contaminant concentrations, incorrect data presentation, etc.
- Failure to address degradation products or intermediates that are sometimes identified as "tentatively identified compounds"
- Inclusion of hazardous substances found in "hot spot" areas for the entire site

On dose-response evaluation:

- Use of out-of-date toxicity values(the RfD and slope factor reviewed by EPA and available on-line from the Integrated Risk Information System (IRIS) should have been used - if values are not available on IRIS, the most recent issue of the Health Effects Assessment Summary Tables should be used)
- Assumption that the toxicity value for one exposure route is applicable to another exposure route without examining the underlying scientific basis (pharmacokinetics)
- Failure to address bioavailability (whether the hazardous substance in the medium matrix is readily available for absorption) and the extent of absorption (how much the hazardous substance in the medium may be absorbed) by the receptor.

On exposure assessment:

- Use of unrealistic exposure assumptions (the "reasonable maximum exposure" (RME) concept should be applied). Refer to "Human Health Evaluation Manual, Supplemental Guidance:Standard Default Exposure Factors" (OSWER Directive 9285.6-03) and "Supplemental Guidance to RAGS: Calculating the Concentration Term" (OSWER Directive 9285.7-08l). Also note that EPA continues to evaluate methods for developing reasonably conservative exposure estimates, such as the RME.)

- Site-specific exposure information (i.e., activity patterns, frequency, and duration) not incorporated in the assessment
- Use of incorrect averaging time to modify daily average intake
- Failure to include physical/biological degradation
- Inappropriate selection of exposure models or use of overly conservative models to predict exposure point concentrations without identifying it as an uncertainty
- Complete exposure pathways identified in the conceptual model are not addressed
- Failure to integrate site-specific atmospheric, geological, and hydrogeological information in the exposure pathway analysis
- Insufficient basis for the use of the entire set or a subset of data to compile exposure point concentrations
- Failure to consider possible exposure routes through the food chain

On risk characterization:

- Conversion error (exposure concentrations not converted to the same unit of measure used in the daily average intake calculations)
- Use of inappropriate assumptions in the biokinetic uptake model to assess the impact of soil lead on blood lead
- Failure to use subchronic toxicity values in assessing less than long-term exposure
- Inadequate uncertainty analyses
- Failure to address the risks from all pertinent site-related hazardous substances (i.e., radionuclides *and* chemicals).

What does "Reasonable Maximum Exposure"(RME) mean?

The National Oil and Hazardous Substances Pollution Contingency Plan (NCP) and the EPA's Human Health Evaluation Manual, Part A(HHEM) provide guidance for using RME in CERCLA risk assessments. A few key concepts follow:

- RME is defined as "...the highest exposure that is reasonably expected to occur at a site. RMEs are estimated for individual pathways. If a population is exposed via more than one pathway, the combination of exposure across pathways also must represent an RME." (HHEM, pg. 6-4)
- "Each intake variable in the [exposure assessment] equation has a range of values...the combination of all intake variable results in an estimate of RME for that pathway.. based on quantitative information, professional judgment, site information or the needs of the risk manager." (HHEM, pg. 6-19)
- "An assumption of future residential land use may not be justifiable if the probability that the site will support residential use in the future is small." [NCP, preamble, Section 300.430(d)]
- EPA "...recommended against the use of unrealistic exposure scenarios and assumptions...the likelihood of exposure actually occurring should be considered when deciding the appropriate level of remediation, to the degree that this likelihood can be determined." [NCP, preamble, Section 300.430(d)]
- Further guidance for developing an RME estimate is provided in the EPA Risk Assessment Council's "Guidance for Risk Assessment" (dated November 1991 and formally conveyed to EPA risk assessors and risk managers as an appendix to a February 16, 1992, memorandum from EPA's Deputy Administrator - see below).

How should baseline risk assessment results be communicated to decision-makers and the public?

In his memorandum conveying "Guidance on Risk Characterization for Risk Managers and Risk Assessors" dated February 26, 1992, EPA Deputy Administrator F. Henry Habicht observed that the results of risk assessments often are boiled down to a point estimate of risk, and that this "short hand"form of risk communication does not adequately convey the full range of information necessary to support informed interpretation of those results. He noted that EPA's Risk Assessment Council pondered this problem and reached the following conclusions: "1. We need to present a full and complete picture of risk, including a statement of confidence about data and methods used to develop the assessment; 2. we need to provide a basis for greater consistency and comparability in risk assessments across Agency programs; and 3. professional scientific judgement plays an important role in the overall statement of risk."

With respect to the first finding, Mr. Habicht stressed that risk assessors must be fully candid regarding the level of confidence and uncertainties inherent in assessment results. He stated that "Numerical risk estimates should always be accompanied by descriptive information carefully selected to ensure an objective and balanced characterization of risk..." Consistency and comparability in risk assessments (conclusion #2 above) will be fostered by adherence to terminology established in EPA's recently revised Guidelines for Exposure Assessment (see May 29, 1992, Federal Register). Also, using several risk descriptors will better represent the range of different exposure and risk conditions that various exposed populations encounter. Finally, professional scientific judgement must be used to determine the extent of risk information that will most effectively convey pertinent risk assessment results. Effective risk characterization should include "...only the most significance data and uncertainties from the assessment (those that define and explain the main risk conclusions) so that decision-makers and the public are not overwhelmed by valid but secondary information."

Note: The primary focus of this Information Brief is the Human Health Evaluation. Ecological evaluation will be covered in a separate Information Brief.

Questions of policy or questions regarding policy decisions will not be dealt with in EH-231 Information Briefs unless that policy has already been established through appropriate documentation. Please refer any questions concerning the subject material covered in this Information Brief to John Bascietto, RCRA/ CERCLA Division, EH-231, FTS 896-7917.